109TH CONGRESS
2D SESSION

S. _____

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to improve drug safety and oversight, and for other purposes.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to improve drug safety and oversight, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Enhancing Drug Safety and Innovation Act of 2006''.

TITLE I—RISK EVALUATION AND MITIGATION STRATEGIES

SEC. 101. RISK EVALUATION AND MITIGATION STRATEGIES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(o) RISK EVALUATION AND MITIGATION STRATEGY.—

''(1) IN GENERAL.—In the case of any drug, except a vaccine or a blood product, subject to subsection (b) or (j) or section 351 of the Public Health Service Act for which a risk evaluation and mitigation strategy is approved as provided for in this subsection, the applicant shall comply with the requirements of such strategy, which—

''(A) shall require the minimal elements required under paragraph (2); and

''(B) may require—

''(i) one or more goals to evaluate or mitigate a serious risk listed in the labeling of the drug or to identify unexpected serious risks of the drug; and

''(ii) additional elements under paragraph (3) or (4), as necessary, taking into consideration such goals, to communicate

about, assess, or manage a serious risk listed in the labeling of the drug or to identify or assess serious unexpected risks.

"(2) REQUIRED ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—A risk evaluation and mitigation strategy shall require the following elements—

"(A) labeling for the drug for use by health care providers;

"(B) submission of reports for the drug required under subsection (k);

"(C) a surveillance plan, that includes a delineation of the role of the applicant and the Secretary, to assess further any serious risk listed in the labeling of the drug and to identify, as appropriate, any unexpected serious risk of the drug, considering—

"(i) the number of patients who are expected to use the drug or, if the drug is approved, who are estimated to be using the drug, and their expected or observed comorbidities;

"(ii) the seriousness of the underlying disease or condition that the drug is used to treat;

"(iii) the expected or actual duration of treatment with the drug;

"(iv) the availability of a comparator drug or other treatment, if any, for such disease and condition; and

"(v) the seriousness of the risk at issue and its background incidence in the population; and

"(D) a timetable for submission of assessments of the strategy, which shall be no less frequently than once annually for the first 3 years after the drug is initially approved under subsection (c) or licensed under section 351 of the Public Health Service Act.

"(3) ADDITIONAL POTENTIAL ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—To communicate about, assess, or manage a serious risk listed in the labeling of the drug, or to identify or assess an unexpected serious risk of the drug, the risk evaluation and mitigation strategy for the drug may require that—

"(A) the applicant develop nonpromotional labeling that is written in nontechnical, understandable language for patients (to be made available at the discretion of the applicant to

health care providers, pharmacists, and patients) if, with respect to such drug, the Secretary determines that such labeling may help—

"(i) assure the effectiveness of the drug; or

"(ii) minimize a serious risk listed in the labeling of the drug;

"(B) the applicant develop a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), for distribution to each patient when the drug is dispensed;

"(C) the applicant conduct a communication plan to physicians, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy under subparagraph (D), (E), or (F) or under paragraph (4), which may include—

"(i) letters to health care providers;

"(ii) information to educate health care providers about the elements of the risk evaluation and mitigation strategy and encourage their compliance with compo-

nents that apply to such health care providers, or to explain certain safety protocols (such as screening and monitoring); or

''(iii) educating health care providers through professional societies about any serious risks of the drug and how to prescribe and use the drug safely;

''(D) the applicant include a black box warning in the labeling of the drug about a serious risk of the drug;

''(E) the applicant or the Secretary conduct an appropriate post-approval study of the drug (with target commencement and completion dates) to assess an empirical signal of a serious risk with use of the drug or to screen for serious risks in domestic populations who may use the drug but were not included in studies used to approve the drug (such as older people, people with comorbidities, pregnant women, or children), such as a prospective or retrospective observational study using—

''(i) a large database derived from medical care systems;

''(ii) a voluntary registry;

''(iii) case controls; or

"(iv) cohorts;

"(F) for a drug for which there is no effective approved application under subsection (j) as of the date that the requirement is first imposed, the applicant conduct an appropriate post-approval clinical trial of the drug (with target commencement and completion dates), to be included in the clinical trial registry database and clinical trial results database provided for under section 402(j) of the Public Health Service Act, if the Secretary determines that the clinical trial is necessary, and that a study under subparagraph (E) will likely be inadequate, to assess an empirical signal of a serious risk with use of the drug (which shall not include a risk that is merely biologically plausible) derived from—

"(i) a clinical trial;

"(ii) adverse event reports;

"(iii) a post-approval study, including a study under subparagraph (E); or

"(iv) peer-reviewed literature;

"(G) the applicant submit to the Secretary advertisements of the drug for preclearance, if the Secretary determines that such clearance is

necessary to ensure compliance with section 502(n) with respect to the disclosure of information about a serious risk listed in the labeling of the drug;

''(H) the applicant include a specific disclosure in advertisements of the drug, if the Secretary determines that advertisements lacking such disclosure would be false or misleading or that such disclosure is necessary to protect public health and safety—

''(i) of the date the drug was approved and that the data used to approve the drug, and the information collected since approval of the drug, may not have identified all significant, serious risks of using the drug;

''(ii) about a serious risk listed in the labeling of the drug; or

''(iii) about a protocol to ensure safe use described in the labeling of the drug; or

''(I) for a fixed period after initial approval, not to exceed 2 years, the applicant not issue or caused to be issued direct-to-consumer advertisements of the drug, if the Secretary de-

termines that such prohibition is necessary to protect public health and safety while additional information about serious risks of the drug is collected, considering—

"(i) the number of patients who may be treated with the drug;

"(ii) the seriousness of the condition for which the drug will be used;

"(iii) the serious risks listed in the labeling of the drug;

"(iv) whether there are other approved drugs in the pharmacological class of the drug or with the same intended use as the drug; and

"(v) the extent to which studies used to approve the drug were insufficiently statistically powered to identify potential serious risks of the drug that might occur in significant numbers among the patients expected to be treated with the drug.

"(4) RESTRICTIONS ON DISTRIBUTION AND USE.—

"(A) IN GENERAL.—If the Secretary determines that a drug presents a substantial risk to public health, the risk evaluation and mitigation

strategy may also require restrictions on distribution and use to address such risk of the drug, as long as such restrictions are—

"(i) commensurate with the risk;

"(ii) necessary to ensure safe use of the drug given the risk; and

"(iii) not unduly burdensome on patient access to the drug.

"(B) ELEMENTS.—The restrictions on distribution and use described under subparagraph (A) may require that—

"(i) health care providers that prescribe the drug have particular training or experience, or elect to be specially certified;

"(ii) pharmacies, practitioners, or health care settings that dispense the drug be specially certified;

"(iii) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

"(iv) each patient using the drug be subject to certain monitoring; or

"(v) each patient using the drug be enrolled in a registry.

"(C) COMPLIANCE SYSTEM.—The restrictions on distribution and use described under subparagraph (A) shall require a compliance system through which the applicant shall—

"(i) monitor and evaluate compliance with the restrictions by health care providers, pharmacists, patients, and other parties in the health care system who are responsible for implementing the restrictions;

"(ii) work to increase adherence to the restrictions by health care providers, pharmacists, patients, and other parties in the health care system who are responsible for implementing the restrictions; and

"(iii) prohibit participation by those health care providers, pharmacists, and other parties in the health care system—

"(I) who are responsible for implementing the restrictions; and

"(II) whom the applicant knows have failed to meet their responsibilities for implementing the restrictions.

"(5) SUBMISSION AND REVIEW OF RISK EVALUATION AND MITIGATION STRATEGY.—

"(A) PROPOSED RISK EVALUATION AND MITIGATION STRATEGY.—An applicant shall include in an application, except in an application for a vaccine or blood product, under subsection (b) or section 351 of the Public Health Service Act (including in a supplemental application seeking a new indication if no risk evaluation and mitigation strategy for the drug is in effect under this subsection) a proposed risk evaluation and mitigation strategy, which—

"(i) shall include the minimal elements required under paragraph (2); and

"(ii) may also include additional elements as provided for under paragraphs (3) and (4).

"(B) ASSESSMENT AND MODIFICATION OF A RISK EVALUATION AND MITIGATION STRATEGY.—

"(i) IN GENERAL.—The applicant may submit an assessment of, and propose a modification to, the approved risk evaluation and mitigation strategy for a drug at any time, and shall submit such an assessment, which may propose such a modification—

''(I) when submitting a supplemental application for a new indication under subsection (b) or section 351 of the Public Health Service Act;

''(II) when required by the strategy, as provided for in the timetable under paragraph (2)(D);

''(III) within a time specified by the Secretary, not to be less than 45 days, when ordered by the Secretary if the Secretary determines that new information indicates that an element under paragraph (2) or (3) should be modified or included in the strategy;

''(IV) within 90 days when ordered by the Secretary if the Secretary determines that new information indicates that an element under paragraph (4) should be modified or included in the strategy; or

''(V) within 15 days when ordered by the Secretary if the Secretary determines that there may be a cause for action by the Secretary under subsection (e).

"(ii) ASSESSMENT.—An assessment of the performance and adequacy of the approved risk evaluation and mitigation strategy for a drug shall include—

"(I) with respect to any goal for the strategy, an assessment of whether the strategy is meeting the goal or whether the goal should be modified;

"(II) with respect to any post-approval study required under paragraph (3)(E), the status of such study, the expected completion date, and whether any difficulties completing the study have been encountered; and

"(III) with respect to any post-approval clinical trial required under paragraph (3)(F), whether enrollment has begun, the number of participants enrolled, the expected completion date, and whether any difficulties completing the study have been encountered.

"(iii) MODIFICATION.—A modification (whether an enhancement or a reduction)

to the approved risk evaluation and mitigation strategy for a drug may include the addition or modification of any element under paragraph (2) or the addition, modification, or removal of any element under paragraph (3) or (4), such as—

''(I) a labeling change;

''(II) adding a post-approval study or clinical trial requirement;

''(III) modifying a post-approval study or clinical trial requirement (such as a modification due to legitimate difficulties recruiting participants);

''(IV) adding, modifying, or removing a restriction on distribution or use; or

''(V) modifying the timetable for assessments of the strategy under paragraph (2)(D), including to reduce the frequency of assessments, or remove the requirements for periodic assessments, if the Secretary determines that the serious risks, if any, of the

drug have been adequately identified, assessed, and managed.

''(C) REVIEW.—The Secretary shall promptly review the proposed risk evaluation and mitigation strategy for a drug submitted under paragraph (A), or an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B).

''(D) DISCUSSION.—The Secretary shall initiate discussions of the proposed risk evaluation and mitigation strategy for a drug submitted under subparagraph (A), or of an assessment of the approved risk evaluation and mitigation strategy for a drug submitted under subparagraph (B), with the applicant to negotiate a mutually agreeable strategy—

''(i) when submitted as part of an application or supplemental application under subparagraph (A) or (B)(i)(I), not less than 60 days before the action deadline for the application that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected

under section 736 to expedite the drug development process and the review of human drug applications);

"(ii) when submitted under subparagraph (B)(i)(II) or (III), not later than 20 days after such submission;

"(iii) when submitted voluntarily by the applicant or under subparagraph (B)(i)(IV), not later than 30 days after such submission; or

"(iv) when submitted under subparagraph (B)(i)(V), not later than 10 days after such submission.

"(E) ACTION.—Unless the applicant requests the dispute resolution process described under subparagraph (F), the Secretary shall approve and describe the risk evaluation and mitigation strategy for a drug, or any modification to the strategy—

"(i) as part of the action letter on the application, when a proposed strategy is submitted under subparagraph (A) or an assessment of the strategy is submitted under subparagraph (B)(i)(I); or

"(ii) in an order, which shall be made public, issued not later than 50 days after the date discussions of such modification begin under subparagraph (C), when an assessment of the strategy is submitted voluntarily by the applicant or under subclause (II), (III), (IV), or (V) of subparagraph (B)(i).

"(F) DISPUTE RESOLUTION.—

"(i) REQUEST FOR REVIEW.—Not earlier than 20 days, and not later than 45 days, after discussions under subparagraph (D) have begun to negotiate a mutually agreeable risk evaluation and mitigation strategy, the applicant may request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board.

"(ii) SCHEDULING REVIEW.—If the applicant requests review under clause (i), the Secretary shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable, or the Secretary may convene a

special meeting of the Drug Safety Oversight Board to review the matter more promptly.

''(iii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under clause (vi), the Secretary and the applicant may reach an agreement on the risk evaluation and mitigation strategy, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the mutually agreeable strategy.

''(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight Board described in clause (ii), the Board shall—

''(I) hear from both parties; and

''(II) review the dispute.

''(v) RECOMMENDATION OF THE BOARD.—No later than 5 days after such meeting of the Drug Safety Oversight Board, the Board shall provide a written recommendation on resolving the dispute to the Secretary.

''(vi) ACTION BY THE SECRETARY.—

''(I) ACTION LETTER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A) or to an assessment of the strategy submitted under subparagraph (B)(i)(I), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

''(aa) the action deadline referred to in subparagraph (D)(i); or

''(bb) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(II) ORDER.—With respect to an assessment of the risk evaluation and mitigation strategy submitted voluntarily by the applicant or under subclause (II), (III), (IV), or (V) of subparagraph (B)(i), the Secretary shall issue an order, which shall be made public, that resolves the dispute not later than 7 days after receiving

the recommendation of the Drug Safety Oversight Board.

''(vii) EFFECT ON ACTION DEADLINE.—With respect to the application or supplemental application in which a proposed risk evaluation and mitigation strategy is submitted under subparagraph (A) or in which an assessment of the strategy is submitted under subparagraph (B)(i)(I), the Secretary shall be considered to have met the action deadline referred to in subparagraph (D)(i) with respect to such application if the applicant requests the dispute resolution process described in this subparagraph and if the Secretary—

''(I) has initiated the discussions described under such subparagraph not less than 60 days before such action deadline; and

''(II) has complied with the timing requirements of scheduling review, providing a written recommendation, and issuing an action letter under clauses (ii), (v), and (vi), respectively.

''(G) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

''(i) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has convened, after appropriate public notice, one or more public meetings to consider possible responses to such concern.

''(ii) PUBLIC MEETINGS.—Such public meetings may include—

''(I) one or more meetings of the applicants for such drugs;

''(II) one or more meetings of an appropriate scientific advisory committee; and

''(III) one or more workshops of scientific experts and other stakeholders.

''(iii) ACTION.—After considering the discussions from any meetings under clause (ii), the Secretary may—

"(I) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

"(II) seek public comment about such action; and

"(III) after seeking such comment, issue an order addressing such regulatory action.

"(H) INTERNATIONAL COORDINATION.—To the extent practicable, the Secretary shall coordinate elements of the risk evaluation and mitigation strategy for a drug, such as the timetable for submission of assessments under paragraph (2)(D), a study under paragraph (3)(E), or a clinical trial under paragraph (3)(F), with efforts to manage the serious risks of the drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States.".

SEC. 102. ENFORCEMENT.

(a) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a drug subject to an approved risk evaluation and mitigation strategy under section 505(o) and the applicant for such drug fails to—

''(1) make a labeling change required by the Secretary after the Secretary has completed review of, and acted on, an assessment of such strategy under paragraph (5) of such section; or

''(2) comply with a requirement of such strategy with respect to advertising as provided for under subparagraph (G), (H), or (I) of paragraph (3) of such section.''.

(b) CIVIL PENALTIES.—Section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (3), (4), and (5) as paragraphs (4), (5), and (6), respectively;

(2) by inserting after paragraph (2) the following:

''(3) An applicant (as such term is used in section 505(o)) who knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under such section 505(o) shall be

subject to a civil money penalty of not less than $15,000 and not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.'';

(3) in paragraph (2)(C), by striking ''paragraph (3)(A)'' and inserting ''paragraph (4)(A)'';

(4) in paragraph (4), as so redesignated, by striking ''paragraph (1) or (2)'' each place it appears and inserting ''paragraph (1), (2), or (3)''; and

(5) in paragraph (6), as so redesignated, by striking ''paragraph (4)'' each place it appears and inserting ''paragraph (5)''.

SEC. 103. CONFORMING AMENDMENTS.

(a) REGULATION OF BIOLOGICAL PRODUCTS.—Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended by inserting '', including the requirements under section 505(o) of such Act,'' after '', and Cosmetic Act''.

(b) CONTENT OF A NEW DRUG APPLICATION.—Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(1) in subparagraph (F), by striking ''and''; and

(2) in subparagraph (G), by striking the period and inserting the following: ", and (H) a proposed risk evaluation and mitigation strategy as described under subsection (o).".

(c) WITHDRAWAL OR SUSPENSION OF APPROVAL.—Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: "The Secretary may withdraw the approval of an application submitted under subsection (b) or (j), or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under subsection (o)(5)(B)(V).".

(d) DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is amended by adding at the end the following:

"(D) RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENT.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to each element of the risk evaluation and mitigation strategy required under subsection (o) for the applicable listed drug, except for any post-approval clinical trial

requirement described under paragraph (3)(F) of such subsection.''.

(e) NO EFFECT ON MANUFACTURING CHANGES THAT DO NOT REQUIRE PREAPPROVAL.—Subsection (d) of section 506A (21 U.S.C. 356a) of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

''(4) ASSESSMENT OF RISK EVALUATION AND MITIGATION STRATEGY.—In the case of a manufacturing change to which this subsection applies for which the submission of a supplemental application is not required under paragraph (1)(A) or for which distribution of the drug involved may commence upon the receipt by the Secretary of a supplemental application for the change under paragraph (3)(B)(ii), the submission of an assessment of the approved risk evaluation and mitigation strategy for the drug under subsection (o)(5)(B) is not required.''.

(f) USER FEES.—Subparagraph (F) of section 735(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(6)) is amended to read as follows:

''(F) Reviewing risk evaluation and mitigation strategies, and collecting, developing, and reviewing safety information on drugs, includ-

ing adverse event reports, and conducting post-approval studies.''.

SEC. 104. DRUG LABELING.

(a) DATABASE OF DRUG LABELING.—Not later than the effective date of this title, the Secretary of Health and Human Services (referred to in this Act as the ''Secretary''), through the Commissioner of Food and Drugs, shall establish a searchable database accessible through a link on the homepage of the Internet website of the Food and Drug Administration through which the Secretary shall make accessible to the public the approved professional labeling and any required patient labeling of each drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) POSTING UPON APPROVAL.—The Secretary, through the Commissioner of Food and Drugs, shall post the approved professional labeling and any required patient labeling of a drug approved under such section 505 or licensed under such section 351 not later than 5 days after the date the drug is approved, including in a supplemental application with respect to a labeling change.

(c) POSTING WITH RESPECT TO DRUGS APPROVED BEFORE EFFECTIVE DATE.—Not later than 12 months

after the effective date of this title, the Secretary shall post the approved professional labeling and any required patient labeling for a drug approved under such section 505 or licensed under such section 351 before the effective date of this title. In carrying out the preceding sentence, the Secretary shall give priority to—

(1) drugs for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(2) drugs deemed to have a risk evaluation and mitigation strategy under subsection (c) of section 105; and

(3) drugs that are most widely prescribed for use by patients.

(d) MEDICATION GUIDES.—Not later than the effective date of this title, the Secretary, through the Commissioner of Food and Drugs, shall establish on the Internet website page for the database required under subsection (a) a link to a list of each drug, whether approved under such section 505 or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required.

SEC. 105. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATE.—This title shall take effect 90 days after the date of enactment of this Act.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—The following drugs approved before the effective date of this title shall be deemed to have an approved risk evaluation and mitigation strategy under such section 505(o):

(A) A drug for which there are in effect on the effective date of this title restrictions on distribution and use required under subpart H of part 314, title 21 of the Code of Federal Regulations, or otherwise agreed to by the applicant and the Secretary for such drug.

(B) A drug approved after October 1, 2002, under a human drug application or supplement (as defined in section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g), for which there is in effect, on the effective date of this title—

(i) a black box warning; or

(ii) a Medication Guide as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations).

(2) RISK EVALUATION AND MITIGATION STRATEGY.—The approved risk evaluation and mitigation strategy deemed in effect for a drug under paragraph (1) shall consist of the elements described in subparagraphs (A) and (B) of paragraph (2) of such section 505(o) and the black box warning, Medication Guide, or restrictions on distribution and use in effect for such drug on the effective date of this title.

(3) NOTIFICATION.—Not later than the effective date of this title, the Secretary shall notify the applicant for each drug described in paragraph (1)—

(A) that such drug is deemed to have an approved risk evaluation and mitigation strategy pursuant to such paragraph; and

(B) of the date, which shall be no sooner than 6 months after the applicant is so notified, by which the applicant shall submit to the Secretary an assessment of such approved strategy under paragraph (5)(B) of such section 505(o).

(4) ENFORCEMENT ONLY AFTER ASSESSMENT AND REVIEW.—Neither the Secretary nor the Attorney General may seek to enforce a requirement of a risk evaluation and mitigation strategy deemed in ef-

fect under paragraph (1) before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505(o).

(c) OTHER DRUGS APPROVED BEFORE THE EFFECTIVE DATE.—The Secretary, on a case-by-case basis, may require the applicant for a drug approved before the effective date of this title to which subsection (b) does not apply to submit an assessment and proposed risk evaluation and mitigation strategy as provided for in paragraph (5)(B) of such section 505(o) if the Secretary determines that there is information with respect to such drug that indicates that—

(1) an element described under paragraph (2)(A) of such section 505(o) may require modification; or

(2) a standard for adding an element described in paragraph (3) or (4) that is not in effect with respect to such drug may apply to such drug.

SEC. 106. STRATEGIC PLAN ON INFORMATION TECHNOLOGY.

Not later than 180 days after the date of enactment of this title, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appro-

priations of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology needed by the Food and Drug Administration to comply with the requirements of this title (and the amendments made by this title);

(2) an assessment of the extent to which the current information technology assets of the Food and Drug Administration are sufficient to meet the needs assessment under paragraph (1);

(3) a plan for enhancing the information technology assets of the Food and Drug Administration toward meeting the needs assessment under paragraph (1); and

(4) an assessment of additional resources needed to so enhance the information technology assets of the Food and Drug Administration.

TITLE II—REAGAN-UDALL INSTITUTE FOR APPLIED BIOMEDICAL RESEARCH

SEC. 201. THE REAGAN-UDALL INSTITUTE FOR APPLIED BIOMEDICAL RESEARCH.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter H—Establishment of Reagan-Udall Institute for Applied Biomedical Research

"SEC. 360. ESTABLISHMENT AND FUNCTIONS OF THE INSTITUTE.

''(a) IN GENERAL.—There is established within the Food and Drug Administration an Institute to be known as the Reagan-Udall Institute for Applied Biomedical Research (referred to in this subchapter as the 'Institute'). The Institute shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e).

''(b) PURPOSE OF INSTITUTE.—The purpose of the Institute is to advance the Critical Path Initiative of the Food and Drug Administration to modernize medical product development and enhance product safety by—

''(1) initiating, sponsoring, and organizing collaborative and multidisciplinary research in the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, and drugs;

''(2) ensuring the broad participation of academic, government, and industrial researchers in the work of the Institute; and

''(3) ensuring the maximum distribution and utilization of the outcomes of such research, including through publication of research results and dissemination of intellectual property generated by the Institute.

''(c) DUTIES OF THE INSTITUTE.—The Institute shall—

''(1) establish goals and priorities relating to the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, and drugs;

''(2) identify unmet needs in the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, and drugs;

''(3) assess existing and proposed Federal research and development programs relating to such sciences, facilitate and encourage interagency coordination of such programs, and expand such programs relating to such sciences, including—

''(A) the identification and validation of biomarkers for use in diagnostic, device, and drug development;

''(B) the development and validation of animal models for human disease;

''(C) pharmacogenomics and inter-individual variability in drug response;

''(D) the development of data analysis technology for use in drug and device development;

''(E) clinical trial design;

''(F) toxicological quality assessment technologies; and

''(G) other related matters consistent with the purposes of the Institute, as determined necessary by the Board;

''(4) award grants to, or enter into contracts or cooperative agreements with, scientists and entities to advance the purposes of the Institute pursuant to the processes established in the by-laws under subsection (d)(2)(A);

''(5) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents, and techniques for use by the Food and Drug Administration, corporate sponsors, nonprofit organizations, and academic and industrial researchers;

''(6) ensure that—

''(A) action is taken as necessary to obtain patents for inventions developed by the Institute or with funds from the Institute;

''(B) action is taken as necessary to enable the licensing of inventions developed by the Institute or with funds from the Institute; and

''(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments promote, to the maximum extent practicable, the broadest transfer and conversion to commercial and noncommercial applications of licensed and patented inventions of the Institute consistent with subsection (b)(3);

''(7) recruit scientists and hold or sponsor (in whole or in part) meetings as appropriate to further the purposes of the Institute;

''(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies;

''(9) conduct annual audits of research activities that are supported by the Institute; and

''(10) carry out such other activities consistent with the purposes of the Institute as the Board determines appropriate.

''(d) BOARD OF DIRECTORS.—

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Institute shall have a Board of Directors (referred to in this subchapter as the 'Board'), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

''(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be—

''(i) the immediate past Chair of Board of Directors of the Institute;

''(ii) the Commissioner of Food and Drugs; and

''(iii) the Director of the National Institutes of Health.

''(C) APPOINTED MEMBERS.—

''(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 12 individuals. Of such appointed members—

''(I) 3 shall be representatives of the general pharmaceutical, device, and biotechnology industries;

"(II) 1 shall be a representative of the general biomedical research field;

"(III) 3 shall be representatives of the Food and Drug Administration;

"(IV) 2 shall be representatives of the National Institutes of Health;

"(V) 1 shall be a representative of the Institute of Medicine;

"(VI) 1 shall be a representative of academic research organizations; and

"(VII) 1 shall be a representative of patient advocacy organizations.

"(ii) REQUIREMENT.—Not less than—

"(I) 3 of the individuals described under clause (i) shall have a background in clinical pharmacology; and

"(II) 2 of such individuals shall have a background in medical device engineering or in biomedical engineering.

"(2) DUTIES OF BOARD.—The Board shall—

"(A) establish by-laws for the Institute that—

"(i) are published in the Federal Register and available for public comment;

"(ii) establish licensing, distribution, and publication policies that support the widest and least restrictive use by the public of information and inventions developed by the Institute or with Institute funds to carry out the duties described in paragraphs (5) and (6) of subsection (c);

"(iii) specify criteria and processes for the review of proposals and awarding of grants and contracts that include peer review and that are substantially consistent with those established by other government organizations, such as the National Institutes of Health and the National Science Foundation;

"(iv) specify a process for annual Board review of the operations of the Institute; and

"(v) establish specific duties of the Executive Director;

"(B) identify and prioritize the scientific needs that may be effectively and uniquely addressed by the Institute;

"(C) prioritize and provide overall direction to the research activities of the Institute;

"(D) evaluate the performance of the Executive Director; and

"(E) carry out any other necessary activities regarding the functioning of the Institute.

"(3) ADDITIONAL BOARD FUNCTIONS.—

"(A) IN GENERAL.—The Board may establish 1 or more Critical Path Institutes to conduct multidisciplinary and collaborative research, education, and outreach, and to modernize the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, and drugs.

"(B) ELIGIBILITY.—To be eligible to host a Critical Path Institute described in subparagraph (A), an entity shall—

"(i) be a State or local government, institution of higher education, or nonprofit entity with demonstrated ability, personnel, and clinical and other technical expertise to undertake the duties con-

sistent with the activities in subparagraph (A); and

''(ii) submit to the Board an application at such time, in such manner, and containing such information as the Board may require.

''(4) CHAIR.—The ex officio members of the Board under paragraph (1)(B) shall designate an appointed member of the Board to serve as the Chair of the Board.

''(5) TERMS AND VACANCIES.—

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the ex officio members of the Board in the

manner described under paragraph (1)(C)(i).

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed by the ex officio members of the Board in the manner described under paragraph (1)(C)(i) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(6) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Institute

and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner of Food and Drugs.

''(f) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) hire 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(2) hire, promote, compensate, and discharge officers and employees of the Institute;

''(3) prescribe the manner in which—

''(A) officers, employees, and agents of the Institute are selected;

''(B) real or personal property of the Institute is acquired, held, and transferred;

''(C) general operations of the Institute are to be conducted; and

''(D) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the informa-

tion, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Institute under subsection (g);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Institute;

''(8) appoint other groups of advisors as may be determined necessary to carry out the functions of the Institute; and

''(9) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this subchapter.

''(g) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may accept on behalf of the Institute, any funds, gifts, devises, or bequests of real or personal property made to the Institute from sources outside the Food and Drug Administration, in-

cluding private entities, for the purposes of carrying out the duties of the Institute.

''(h) ANNUAL REPORTS.—

''(1) REPORTS TO INSTITUTE.—Any recipient of a grant, contract, or cooperative agreement from the Institute under this section shall submit to the Institute a report on an annual basis that describes the activities carried out under such grant, contract, or cooperative agreement.

''(2) REPORT TO CONGRESS.—Beginning with fiscal year 2008, the Executive Director shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report that—

''(A) describes the activities of the Institute and of the recipients of a grant, contract, or cooperative agreement under this section;

''(B) provides a specific accounting of the source of all funds used by the Institute to carry out such activities; and

''(C) describes how such funds were used by the Institute.

''(i) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury

are held in separate accounts from funds received from private entities under subsection (g).

''(j) AUTHORIZATION OF APPROPRIATIONS.—

''(1) ADMINISTRATIVE PROVISIONS.—

''(A) IN GENERAL.—There are authorized to be appropriated $20,000,000 for each of fiscal years 2008 through 2013 to carry out this section, section 361, and section 362.

''(B) LIMITATION.—From amounts appropriated for a fiscal year under subparagraph (A), the Secretary shall use not less than $1,200,000 to carry out subsections (a), (b), and (d) through (i).

''(2) LIMITATION.—Beginning with fiscal year 2013, if the Institute fails to collect at least $20,000,000 in funds from private sources for any 2-year period, this subchapter shall cease to have force or effect.''.

(b) EMPLOYEES FROM OTHER FEDERAL AGENCIES.—Chapter VII (21 U.S.C. 380 et seq.) (as amended by subsection (a)) is further amended by adding at the end the following:

"SEC. 361. ACCEPTING EMPLOYEES FROM OTHER FEDERAL AGENCIES.

"(a) COLLABORATION WITH OTHER AGENCIES.—To carry out the purposes of the Institute, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Executive Director of the Institute, may collaborate with other Federal agencies and accept the services of employees from those agencies without reimbursement to those agencies.

"(b) DETAIL OF GOVERNMENT EMPLOYEES.—Not more than 5 Federal Government employees may be detailed to the Institute at any time for a period not to exceed 6 years for each such employee, and such detail shall be without civil service status or privilege. Such employees shall abide by the statutory, regulatory, ethical, and procedural standards applicable to employees of the Food and Drug Administration.

"(c) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.—The Executive Director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

"(d) NO ADDITIONAL LIABILITY.—Nothing in this section adds to any liability that the United States may

have under chapter 171 of title 28, United States Code (commonly known as the Federal Tort Claims Act).''.

(c) OTHER INSTITUTE PROVISIONS.—Chapter VII (21 U.S.C. 371 et seq.) (as amended by subsection (b)) is further amended by adding at the end the following:

''SEC. 362. LOCATION OF INSTITUTE.

''(a) IN GENERAL.—The Institute shall, if practicable, be located not more than 20 miles from the District of Columbia.

''(b) USE OF SPACE.—The Secretary shall consult with the Administrator of General Services to ensure the most cost-efficient arrangement for the leasing or purchase of real property for adequate facilities which, if practicable, shall be located at the Food and Drug Administration, to meet the needs of the Institute in carrying out this subchapter.''.

(d) RECOVERY AND RETENTION OF FEES FOR FOIA REQUESTS.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by subsection (c)) is further amended by adding at the end the following:

"SEC. 363. RECOVERY AND RETENTION OF FEES FOR FREEDOM OF INFORMATION REQUESTS TO THE INSTITUTE.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may—

"(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, United States Code, to recover all reasonable costs incurred in processing requests made under section 552 of title 5, United States Code, for records obtained or created by the Institute under this Act or any other Federal law for which responsibility for administration has been delegated to the Institute by the Secretary;

"(2) retain all fees charged for such requests; and

"(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

"(b) USE OF FEES.—The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1). Such fees shall not be used to reduce the amount of funds made available to carry out other provisions of this Act.

"(c) WAIVER OF FEES.—Nothing in this section shall supersede the right of a requester to obtain a waiver of

fees pursuant to section 552(a)(4)(A) of title 5, United States Code.''.

TITLE III—CLINICAL TRIALS

SEC. 301. CLINICAL TRIAL REGISTRY DATABASE AND CLINICAL TRIAL RESULTS DATABASE.

(a) IN GENERAL.—Section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)) is amended to read as follows:

''(j) CLINICAL TRIAL REGISTRY DATABASE; CLINICAL TRIAL RESULTS DATABASE.—

''(1) DEFINITIONS; REQUIREMENT.—

''(A) DEFINITIONS.—In this subsection:

''(i) CLINICAL TRIAL INFORMATION.—The term 'clinical trial information' means those data elements that are necessary to complete an entry in the clinical trial registry database under paragraph (2) or the clinical trial results database under paragraph (3), as applicable.

''(ii) COMPLETION DATE.—The term 'completion date' means, with respect to a clinical trial, the date on which the clinical trial concluded, was abandoned, or was suspended.

"(iii) DRUG.—The term 'drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

"(iv) RESPONSIBLE PARTY.—The term 'responsible party', with respect to a clinical trial of a drug, means the sponsor of the clinical trial or the principal investigator of such clinical trial if so designated by such sponsor.

"(B) REQUIREMENT.—The Secretary shall develop a mechanism by which—

"(i) the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2); and

"(ii) other Federal agencies may identify the responsible party for an applicable clinical trial.

"(2) CLINICAL TRIAL REGISTRY DATABASE.—

"(A) APPLICABLE CLINICAL TRIAL.—For purposes of this paragraph the term 'applicable clinical trial'—

"(i) means—

"(I) a clinical trial completed before the drug is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act that is—

"(aa) a therapeutic or chemopreventive exploratory trial to verify the efficacy and establish appropriate doses for the drug; or

"(bb) a therapeutic or chemopreventive confirmatory trial; or

"(II) a clinical trial completed after the drug is approved under such section 505 or licensed under such section 351.

"(ii) EXCEPTION.—A clinical trial under clause (i)(I) does not include an exploratory trial that is intended solely to as-

sess safety or solely to evaluate pharmacokinetics.

''(B) ESTABLISHMENT.—To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall establish and administer a clinical trial registry database in accordance with this subsection (referred to in this subsection as the 'registry database'). The Director of NIH shall ensure that the registry database is made publicly available through the Internet.

''(C) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the registry database by—

''(i)(I) the indication being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors; or

''(II) the safety issue being studied in the clinical trial;

''(ii) the phase of the clinical trial;

''(iii) whether enrollment status of the clinical trial is open or closed; and

''(iv) within the document described in subparagraph (D)(ii)(II)—

"(I) the sponsor of the clinical trial;

"(II) each financial sponsor of the clinical trial; and

"(III) the principal investigator of the clinical trial.

"(D) CONTENTS.—

"(i) IN GENERAL.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry database the clinical trial information described in clause (ii).

"(ii) PUBLICLY AVAILABLE ELEMENTS.—In submitting clinical trial information to the Director of NIH for inclusion in the registry database, the responsible party shall include, with respect to such clinical trial, the following information:

"(I) The information described under clauses (i) through (iii) of subparagraph (C).

"(II) A non-promotional summary document that includes the following information:

"(aa) The purpose of the clinical trial outlined in a paragraph.

"(bb) If the drug is currently approved, the pharmacological class description.

"(cc) The sponsor of the clinical trial.

"(dd) Each financial sponsor of the clinical trial.

"(ee) The principal investigator of the clinical trial.

"(ff) Each location of the clinical trial.

"(gg) Contact information for each location of the clinical trial.

"(hh) The inclusion and exclusion criteria of the clinical trial.

"(ii) The target number of subjects to be enrolled in the clinical trial.

"(jj) The expected duration of the clinical trial.

"(kk) If the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, whether or not there is an opportunity to access the drug outside of the clinical trial for those who do not qualify for enrollment in the trial and how to obtain information about such an opportunity.

"(E) TRUTHFUL CLINICAL TRIAL INFORMATION.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

"(F) RESTRICTED ELEMENTS.—

"(i) IN GENERAL.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry database the clinical trial information described in clause (ii). The Director of NIH shall ensure that the information submitted under this subparagraph is not made publicly available.

"(ii) RESTRICTED INFORMATION.—The responsible party shall submit—

"(I) on the date that clinical trial information is first submitted to the Director of NIH—

"(aa) the proposed length of the data analysis period after conclusion of the clinical trial; and

"(bb) the target completion date of the trial; and

"(II) not later than 30 days after the target completion date proposed in subclause (I)(bb), a statement that the clinical trial is complete, or a progress report that includes a revised target completion date for the clinical trial and the reason for the delay.

"(iii) REVISION OF DATE FOR SUBMISSION.—The responsible party for an applicable clinical trial shall have one opportunity to revise the target completion date under clause (ii)(II).

"(iv) ENROLLMENT.—The responsible party for an applicable clinical trial shall

update the enrollment status submitted under subparagraph (C)(iii) not later than 30 days after the enrollment status of such trial closes.

''(v) DURATION.—The responsible party for an applicable clinical trial shall update the expected duration of a clinical trial submitted under subparagraph (D)(ii)(II)(jj) if the expected duration of the clinical trial changes by more than 25 percent.

''(G) TIMING OF SUBMISSION.—The clinical trial information for an applicable clinical trial required to be submitted under this paragraph shall be submitted after such clinical trial is approved by the applicable institutional review boards and before the first patient is enrolled in such clinical trial.

''(3) CLINICAL TRIALS RESULTS DATABASE.—

''(A) APPLICABLE CLINICAL TRIAL.—For purposes of this paragraph, the term 'applicable clinical trial' means—

''(i) a clinical trial completed before the drug is approved under section 505 of the Federal Food, Drug, and Cosmetic Act

or licensed under section 351 of this Act that is—

"(I) a therapeutic or chemopreventive confirmatory trial;

"(II) a clinical trial for a drug approved as a fast-track product under section 506 of the Federal Food, Drug, and Cosmetic Act, if such clinical trial is used to form the primary basis of an efficacy claim for such drug; or

"(III) if required by the Secretary under subparagraph (G)(i), a clinical trial described in paragraph (2)(A)(i)(I)(aa); or

"(ii) a clinical trial completed after the drug is approved under such section 505 or licensed under such section 351.

"(B) ESTABLISHMENT.—To ensure that results of clinical trials are made public and that patients and providers have current information regarding the results of clinical trials, the Secretary, acting through the Director of NIH, shall establish and administer a clinical trial results database in accordance with this

subsection (referred to in this subsection as the 'results database').

''(C) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the results database by—

''(i)(I) the indication studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors; or

''(II) the safety issue studied in the clinical trial;

''(ii) whether an application for the tested indication is approved, pending approval, withdrawn, or not submitted;

''(iii) the phase of the clinical trial;

''(iv) the name of the drug that is the subject of the clinical trial; and

''(v) within the documents described in subclauses (II) and (III) of subparagraph (D)(ii)—

''(I) the sponsor of the clinical trial;

''(II) each financial sponsor of the clinical trial; and

''(III) the principal investigator of the clinical trial.

''(D) CONTENTS.—

''(i) IN GENERAL.—The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the results database the clinical trial information described in clause (ii).

''(ii) REQUIRED ELEMENTS.—In submitting clinical trial information for an applicable clinical trial to the Director of NIH for inclusion in the results database, the responsible party shall include, with respect to such clinical trial, the following information:

''(I) The information described in clauses (i) through (iv) of subparagraph (C).

''(II) A non-promotional summary document that is written in non-technical, understandable language for patients that includes the following:

''(aa) The purpose of the clinical trial.

''(bb) The sponsor of the clinical trial.

"(cc) Each financial sponsor of the clinical trial.

"(dd) The principal investigator of the clinical trial.

"(ee) Contact information for the principal investigator of the clinical trial.

"(ff) A description of patient population tested in the clinical trial.

"(gg) A general description of the clinical trial and results, including—

"(AA) a description of and the reasons for any changes in the clinical trial design that occurred since the date of submission of clinical trial information for inclusion in the registry database established under paragraph (2); and

"(BB) a description of any significant safety information.

"(III) A non-promotional summary document that is technical in nature that includes the following:

"(aa) The purpose of the clinical trial.

"(bb) The sponsor of the clinical trial.

"(cc) Each financial sponsor of the clinical trial.

"(dd) The principal investigator of the clinical trial.

"(ee) Contact information for the principal investigator of the clinical trial.

"(ff) A description of the patient population tested in the clinical trial.

"(gg) A general description of the clinical trial and results, including a description of and the reasons for any changes in the clinical trial design that occurred since the date of submission of clinical trial information for the clinical trial in the registry data-

base established under paragraph (2).

''(hh) Summary data describing the results, including the following:

''(AA) Whether the primary endpoint was achieved, including relevant statistics.

''(BB) An assessment of any secondary endpoints, if applicable, including relevant statistics.

''(CC) Any significant safety information, including a summary of the incidence of serious adverse events observed in the clinical trial and the most common adverse events observed in the clinical trial for which there was a statistically significant increase over the rate observed for the control arm of the clinical trial.

"(IV) Peer-reviewed publications based on the results of the clinical trial, if any.

"(V) The completion date of the clinical trial.

"(VI) A link to the Internet web posting of any adverse regulatory actions taken by the Food and Drug Administration, such as a warning letter, that was substantively based on the clinical trial design, outcome, or representation made by the applicant about the design or outcome of the clinical trial.

"(E) TIMING.—A responsible party shall submit to the Director of NIH for inclusion in the results database clinical trial information for an applicable clinical trial not later than 30 days after—

"(i) the conclusion of the data analysis period described in paragraph (2)(F)(ii)(I)(aa); or

"(ii) the target completion date of the clinical trial as updated under paragraph (2)(F)(iii), if applicable.

"(F) TRUTHFUL CLINICAL TRIAL INFORMATION.—The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

"(G) INCLUSION OF EARLIER CLINICAL TRIALS.—

"(i) IN GENERAL.—The Secretary may, subject to clause (ii), require through rulemaking the submission of clinical trial information for the clinical trials described in paragraph (2)(A)(i)(I)(aa) to the Director of NIH for inclusion in the results database.

"(ii) CONDITIONS FOR REQUIRING INCLUSION OF EARLIER TRIALS.—The Secretary may promulgate regulations pursuant to clause (i) if—

"(I) the Comptroller General of the United States has submitted to the Secretary the report described under clause (iii); and

"(II) such report recommends the inclusion in the results database of clinical trial information for the

clinical trials described under paragraph (2)(A)(i)(I)(aa).

''(iii) STUDY BY GAO.—Not earlier than 2 years after the results database has been established, the Comptroller General of the United States shall initiate a report that—

''(I) evaluates the operation of the database, including with respect to cost, burden on drug sponsors and agencies, and the value of inclusion in the results database of clinical trial information with respect to clinical trials described in paragraph (2)(A)(i)(I)(aa);

''(II) recommends whether or not clinical trial information for such clinical trials should be included in the results database;

''(III) if the recommendation under subclause (II) is to include the clinical trial information for such trial in the results database, recommends whether such information should be included in the same manner as the

clinical trial information of other applicable clinical trials, or if modifications are necessary;

"(IV) provides recommendations for any modifications described under subclause (III);

"(V) is submitted to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Secretary.

"(H) CHANGE IN REGULATORY STATUS.—The responsible party for an applicable clinical trial shall update the regulatory status submitted under subparagraph (C)(ii) of a drug that is the subject of an applicable clinical trial within 30 days of a change in such status.

"(I) PUBLIC AVAILABILITY OF RESULTS.—

"(i) PRE-APPROVAL STUDIES.—Except as provided in clause (iv), with respect to an applicable clinical trial that is completed before the drug is initially approved under section 505 of the Federal Food, Drug, or Cosmetic Act or initially licensed

under section 351 of this Act, the Director of NIH shall make publicly available on the results database the clinical trial information submitted for such clinical trial not later than 30 days after—

"(I) the drug is approved under such section 505 or licensed under such section 351;

"(II) the Secretary issues a not approvable letter for the drug under such section 505 or such section 351; or

"(III) the application under such section 505 or such section 351 is withdrawn.

"(ii) POST-APPROVAL STUDIES.—Except as provided in clauses (iii) and (iv), with respect to an applicable clinical trial that is completed after the drug is initially approved under such section 505 or initially licensed under such section 351, the Director of NIH shall make publicly available on the results database the clinical trial information submitted for such clin-

ical trial not later than 30 days after the date of such submission.

"(iii) SEEKING APPROVAL OF A NEW USE FOR THE DRUG.—

"(I) IN GENERAL.—If the manufacturer of the drug is the sponsor or a financial sponsor of the applicable clinical trial, and such manufacturer certifies to the Director of NIH that such manufacturer has filed, or will file within 1 year, an application seeking approval under such section 505 or licensing under such section 351 for the use studied in such clinical trial (which use is not included in the labeling of the approved drug), then the Director of NIH shall make publicly available on the results database the clinical trial information submitted for such clinical trial on the earlier of the date that is 30 days after the date—

"(aa) the application is approved under such section 505 or licensed such section 351;

"(bb) the Secretary issues a not approvable letter for the application under such section 505 or such section 351; or

"(cc) the application under such section 505 or such section 351 is withdrawn.

"(II) LIMITATION ON CERTIFICATION.—A manufacturer shall not make a certification under subclause (I) with respect to an applicable clinical trial unless the manufacturer makes such a certification with respect to each applicable clinical trial that is required to be submitted in an application for approval of the use studied in the clinical trial involved.

"(III) 2 YEAR LIMITATION.—The clinical trial information subject to subclause (I) shall be made publicly available on the results database on the date that is 2 years after the date that the clinical trial information was required to be submitted to the Director of NIH if a regulatory action re-

ferred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

''(iv) SEEKING PUBLICATION.—

''(I) IN GENERAL.—If the principal investigator of the applicable clinical trial is seeking publication in a peer-reviewed journal of a manuscript based on the results of the clinical trial and the responsible party so certifies to the Director of NIH, the Director of NIH shall make publicly available on the results database the clinical trial information submitted for such trial on the date that is 30 days after the publication date of such manuscript.

''(II) LIMITATION.—The clinical trial information subject to subclause (I) shall be made publicly available on the results database on the date that is 2 years after the date that the clinical trial information was required to be submitted to the Director of NIH if the manuscript referred to in such

subclause has not been published by such date.

''(J) VERIFICATION OF SUBMISSION PRIOR TO PUBLIC AVAILABILITY.—In the case of clinical trial information that is submitted under this paragraph, but is not made publicly available pending either regulatory action or publication under clause (iii) or (iv) of subparagraph (I), as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed journals to verify whether such clinical trial information has been submitted but has not yet been made publicly available on the results database.

''(4) COORDINATION AND COMPLIANCE.—

''(A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES.—

''(i) IN GENERAL.—No Federal agency may release funds under a research grant to a person who has not complied with paragraphs (2) and (3) for any applicable clinical trial for which such person is the responsible party.

''(ii) GRANTS FROM CERTAIN FEDERAL AGENCIES.—If an applicable clinical

trial is funded in whole or in part by a grant from the National Institutes of Health, the Agency for Healthcare Research and Quality, or the Department of Veterans Affairs, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

''(iii) VERIFICATION BY FEDERAL AGENCIES.—The heads of the agencies referred to in clause (ii), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) and (3), as applicable, before releasing funding for a grant to such grantee.

''(iv) NOTICE AND OPPORTUNITY TO REMEDY.—If the head of an agency referred to in clause (ii), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (iii), such agency head shall provide

notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

''(v) CONSULTATION WITH OTHER FEDERAL AGENCIES.—The Secretary shall—

''(I) consult with other agencies that conduct human studies in accordance with section 46 of title 45, Code of Federal Regulations, to determine if any such studies are applicable clinical trials under paragraph (2) or (3); and

''(II) develop with such agencies procedures comparable to those described in clauses (ii), (iii), and (iv) to ensure that clinical trial information for such applicable clinical trials are submitted under paragraphs (2) and (3).

''(B) COORDINATION OF REGISTRY DATABASE AND RESULTS DATABASE.—

''(i) IN GENERAL.—Each entry in the registry database under paragraph (2)

shall include a link to the corresponding entry in the results database under paragraph (3).

''(ii) MISSING ENTRIES.—

''(I) IN GENERAL.—If, based on a review of the entries in the registry database under paragraph (2), the Director of NIH determines that a responsible party has failed to submit required clinical trial information to the results database under paragraph (3), the Director of NIH shall inform the responsible party involved of such failure and permit the responsible party to correct the failure within 30 days.

''(II) FAILURE TO CORRECT.—If the responsible party does not correct a failure to submit required clinical trial information within the 30-day period described under subclause (I), the Director of NIH shall report such non-compliance to the scientific peer review committees of the Federal research agencies and to the Office of

Human Research Subjects Protections.

''(III) PUBLIC NOTICE OF FAILURE TO CORRECT.—The Director of NIH shall include in the clinical trial registry database entry and the clinical trial results database entry for each such clinical trial a notice of any uncorrected failure to submit required clinical trial information and shall provide that the public may easily search for such entries.

''(C) ACTION ON APPLICATIONS.—

''(i) VERIFICATION PRIOR TO FILING.—The Secretary, acting through the Commissioner of Food and Drugs, shall verify that the clinical trial information required under paragraphs (2) and (3) for an applicable clinical trial is submitted pursuant to such applicable paragraph—

''(I) when considering a drug for an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act, including as the drug progresses through the clinical trials de-

scribed under clause (i) of paragraph (2)(A); and

''(II) prior to filing an application under section 505 of the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act that includes information from such clinical trial.

''(ii) NOTIFICATION.—If the responsible party has not submitted such clinical trial information, the Secretary shall notify the applicant and the responsible party of such non-compliance and require submission of such results within 30 days.

''(iii) REFUSAL TO FILE.—If the responsible party does not remedy such non-compliance within 30 days of receipt of notification under clause (iii), the Secretary shall refuse to file such application.

''(D) CONTENT REVIEW.—

''(i) IN GENERAL.—To assure that the summary documents described in paragraph (2)(D) and paragraph (3)(D) are non-promotional, and not false or misleading in any particular, the Secretary

shall compare such documents to the results data of the clinical trial for a representative sample of applicable clinical trials by—

''(I) acting through the Commissioner of Food and Drugs to examine the results data for such clinical trials submitted to Secretary as part of an application under section 505 of the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act, or in an annual status report on the drug under such application;

''(II) acting through the Inspector General of the Department of Health and Human Services and with the Federal agency that funds such clinical trial in whole or in part by a grant to examine the results data for such clinical trials; and

''(III) acting through inspections under section 704 of the Federal Food, Drug, and Cosmetic Act to examine results data for such clinical

trials not described in subclause (I) or (II).

''(ii) NOTICE OF NON-COMPLIANCE.—If the Secretary or Inspector General of the Department of Health and Human Services determines that the clinical trial information submitted in such a summary document is promotional, or false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such non-compliance by submitting the required revised clinical trial information within 30 days of such notification.

''(E) PENALTY FOR NON-COMPLIANCE.—In determining whether to apply a penalty under section 301(hh) of the Federal Food, Drug, and Cosmetic Act, the Secretary, acting through the Commissioner of Food and Drugs, shall consider—

''(i) whether the responsible party promptly corrects the non-compliance when provided notice;

"(ii) whether the responsible party has engaged in a pattern or practice of non-compliance; and

"(iii) the extent to which the non-compliance involved may have significantly misled healthcare providers or patients concerning the safety or effectiveness of the drug involved.

"(5) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—Disclosure to the public of clinical trial information submitted to the Director of NIH under this subsection and requested under section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) shall be made only as provided for in the databases under paragraphs (2) and (3).

"(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary.".

(b) CONFORMING AMENDMENTS.—

(1) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(ii)(1) The failure to submit clinical trial information as required by section 402(j) of the Public Health Service Act.

''(2) The submission of clinical trial information under section 402(j) of the Public Health Service Act that is promotional or false or misleading in any particular.''.

(2) NEW DRUGS.—

(A) INVESTIGATIONAL NEW DRUGS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(i) in paragraph (1)—

(I) in subparagraph (C), by striking ''and'' after the semicolon;

(II) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

(III) by adding at the end the following:

''(E) the submission to the Director of NIH of clinical trial information for the clinical investigation at issue required under section 402(j) of the Public Health Service Act for inclusion in the registry database and the results database described in such section.'';

(ii) in paragraph (3)(B)—

(I) in clause (i), by striking ''or'' after the semicolon;

(II) in clause (ii), by striking the period at the end and inserting ''; or''; and

(III) by adding at the end the following:

''(iii) clinical trial information for the clinical investigation at issue was not submitted in compliance with section 402(j) of the Public Health Service Act.''; and

(iii) in paragraph (4), by adding at the end the following: ''The Secretary shall update such regulations to require inclusion in the informed consent form a statement that, if applicable, clinical trial information for such clinical investigation will be submitted for inclusion in the registry database and results database, if applicable, described in section 402(j) of the Public Health Service Act.''.

(B) REFUSAL TO APPROVE APPLICATION.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended—

(i) in the first sentence, by inserting after ''or any particular;'' the following: ''or (8) the applicant failed to submit the clinical trial information for any clinical trial submitted as part of the application to the Director of the National Institutes of Health in compliance with section 402(j) of the Public Health Service Act;''; and

(ii) in the second sentence, by striking ''clauses (1) through (6)'' and inserting ''(1) through (8)''.

(c) GUIDANCE.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, shall issue guidance to clarify which clinical trials are applicable clinical trials (as defined in section 402(j)(2)) of the Public Health Service Act, as amended by this section) (42 U.S.C. 282(j)(2)) and are required to be submitted for inclusion in the clinical trial registry database described in such section 402(j)(2).

(d) PREEMPTION.—

(1) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION.—The submission of clinical trial information, if submitted in compliance with section 402(j) of the Public Health Service Act (as amended by this section) (42 U.S.C. 282(j)), that relates to a use of a drug not included in the labeling of the approved drug shall not be construed by the Secretary or in any administrative or judicial proceeding, as evidence of a new intended use of the drug that is different from the intended use of the drug set forth in the official labeling of the drug. The availability of clinical trial information through the databases under paragraphs (2) and (3) of such section 402(j), if submitted in compliance with such section 402(j), shall not be considered as labeling, adulteration, or misbranding of the drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(e) EFFECTIVE DATES.—

(1) ESTABLISHMENT OF REGISTRY DATABASE AND RESULTS DATABASE.—Not later than 90 days after the date of enactment of this Act, the Director of NIH shall establish the registry database and the results database of clinical trials of drugs in accordance with section 402(j) of the Public Health Service

Act (42 U.S.C. 282(j)) (as amended by subsection (a)).

(2) CLINICAL TRIALS INITIATED PRIOR TO OPERATION OF REGISTRY DATABASE.—The responsible party (as defined in such section 402(j)) for an applicable clinical trial under paragraph (2) of such section 402(j) that is initiated after the date of enactment of this Act and before the date such registry database is established under paragraph (1) of this subsection, shall submit required clinical trial information not later than 90 days after the date such registry database is established.

(3) CLINICAL TRIALS INITIATED AFTER OPERATION OF REGISTRY DATABASE.—The responsible party (as defined in such section 402(j)) for an applicable clinical trial under paragraph (2) of such section 402(j) that is initiated after the date such registry database is established under paragraph (1) of this subsection, shall submit required clinical trial information in accordance with such paragraph (2).

(4) TRIALS COMPLETED BEFORE OPERATION OF RESULTS DATABASE.—

(A) IN GENERAL.—Paragraph (3) of such section 402(j) shall take effect 90 days after the date the results database is established

under paragraph (1) of this subsection with respect to any applicable clinical trial (as defined in such section 402(j)(3)) that—

(i) involves a drug to treat a serious and life-threatening condition; and

(ii) is completed between the date of enactment of this section and such date of establishment under paragraph (1) of this subsection.

(B) OTHER TRIALS.—Except as provided in subparagraph (A), paragraph (3) of such section 402(j) shall take effect 180 days after the date that the results database is established under paragraph (1) of this subsection with respect to any applicable clinical trial (as defined in such section 402(j)(3)) that is completed between the date of enactment of this Act and such date of establishment under paragraph (1).

(5) TRIALS COMPLETED AFTER ESTABLISHMENT OF RESULTS DATABASE.—Paragraph (3) of such section 402(j) shall apply to any applicable clinical trial that is completed after the date that the results database is established under paragraph (1) of this subsection.

(6) FUNDING RESTRICTIONS.—Subparagraph (A) of paragraph (4) of such section 402(j) shall take effect 90 days after the date that the clinical trial registry database and the clinical trial results database are established under paragraph (1) of this subsection.

(7) STATUS OF CLINICALTRIALS.GOV WEBSITE.—Section 402(j) of the Public Health Service Act (as in effect on the day before the date of enactment of this Act) shall cease to have force or effect upon such date of enactment. The Secretary shall maintain an archive of the clinical trials database provided for under such section 402(j) (as in effect on the day before the date of enactment of this Act) on the Internet website of the National Library of Medicine.

TITLE IV—CONFLICTS OF INTEREST

SEC. 401. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

"SEC. 712. CONFLICTS OF INTEREST.

''(a) DEFINITIONS.—For purposes of this section:

''(1) INVOLVEMENT.—The term 'involvement' means any financial interest in a product, a competing product, in the sponsor of a product, or in the sponsor of a competing product, that may be considered by a panel.

''(2) PANEL.—The term 'panel' means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, that is established by statute or by the Secretary to provide advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

''(3) PRODUCT.—The term 'product' means a food, drug, biological product, device, or electronic product that is regulated by the Food and Drug Administration.

''(b) APPOINTMENTS TO PANELS.—

''(1) DISCLOSURE.—Prior to appointment to a panel, each candidate member of a panel shall disclose to the Secretary all involvements that such candidate may have with the work likely to be undertaken by the panel during the term of the appointment for which the candidate is under consideration.

''(2) EVALUATION AND CRITERIA.—When considering an appointment to a panel, the Secretary—

''(A) shall review the potential involvements of the candidate for appointment relative to the scope of work likely to be undertaken by the panel during the term of the appointment for which the candidate is under consideration, with the goal of appointing individuals with no involvements, or only potential involvements of low magnitude, with such work, and, to the extent practicable, avoiding the appointment of individuals with potential involvements of high magnitude with such work; and

''(B) may appoint 2 or more individuals with similar expertise and non-overlapping or minimally overlapping potential involvements, so as to minimize the likelihood for an appointed individual to require a waiver of a conflict of interest requirement for service on the panel for a meeting of such panel, or for an appointed individual to be recused from service on the panel for a meeting of such panel.

''(c) DISCLOSURE BY PANEL MEMBER.—

''(1) IN GENERAL.—Prior to a meeting of a panel, each member of such panel shall disclose to

the Secretary all involvements that such member may have with the work to be undertaken by such panel at such meeting.

''(2) DETERMINATION BY SECRETARY WITH RESPECT TO PANEL MEETINGS.—

''(A) IN GENERAL.—The Secretary shall make a determination with respect to each panel member based on the disclosure under paragraph (1). Such a determination shall be in one of the following categories:

''(i) APPROVAL FOR SERVICE.—The Secretary shall make the determination of approval for service for a panel member if there is no potential conflict or if the involvements of the panel member are a potential conflict of low magnitude.

''(ii) APPROVAL FOR SERVICE WITH A WAIVER OR LIMITED WAIVER.—The Secretary shall make the determination of approval for service with a waiver or limited waiver for a panel member if the involvements of the panel member are a potential conflict of medium magnitude and the Secretary certifies in writing that—

''(I) such waiver is necessary to provide the panel with essential expertise; or

''(II) the need for the individual's service outweighs the potential for a conflict of interest created by the disclosed involvements.

''(iii) RECUSAL.—The Secretary shall make the determination of recusal for a panel member if—

''(I) any involvement of the panel member is a potential conflict of high magnitude; or

''(II) the involvements of the panel member are a potential conflict of medium magnitude but a waiver or limited waiver could not be granted under clause (ii) because the criteria for a certification by the Secretary under such clause were not met.

''(B) NOTICE OF DETERMINATION.—

''(i) MORE THAN 15 DAYS IN ADVANCE.—Not later than 15 days prior to a meeting of a panel to which a determination for a panel member under clause (ii)

or (iii) of subparagraph (A) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code (popularly known as the Freedom of Information Act)) on the Internet website of the Food and Drug Administration—

''(I) the type of the involvements;

''(II) the nature of the involvements;

''(III) the magnitude of the involvements; and

''(IV) the reasons for any determination of the Secretary under such clause (ii).

''(ii) LESS THAN 15 DAYS IN ADVANCE.—In the case of a conflict of interest that becomes known to the Secretary less than 15 days prior to a meeting to which the determination under clause (ii) or (iii) of subparagraph (A) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code (popularly known as the Freedom of Infor-

mation Act)) on the Internet website of the Food and Drug Administration, the information described in subclauses (I) through (IV) of clause (i) of this subparagraph as soon as practicable, but in no event later than the date of such meeting.

''(d) LIMITATIONS.—In no case—

''(1) may the Secretary grant a waiver under subsection (c)(2) for a panel member if the scientific work of such member is under consideration by the panel; or

''(2) may a panel member vote with respect to any matter considered by the panel if such panel member or an immediate family member of such panel member could gain financially from the advice given to the Secretary with respect to such matter.

''(e) PUBLIC RECORD.—The Secretary shall ensure that the public record of each meeting of a panel includes a description of any determination of the Secretary made under subsection (c)(2), including the category of such determination and the involvements of each panel member (other than information exempted from disclosure under section 552 of title 5, United States Code (popularly known as the Freedom of Information Act)).

''(f) GUIDANCE.—

''(1) NOMINATIONS.—Not later than 270 days after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2006 the Secretary shall publish in the Federal Register for public comment a proposed mechanism for encouraging the nomination of individuals that are classified by the Food and Drug Administration as academicians or practitioners for service on any panel.

''(2) CONFLICT OF INTEREST DETERMINATIONS.—Not later than 270 days after the date of enactment of Enhancing Drug Safety and Innovation Act of 2006 the Secretary shall issue or revise guidance—

''(A) that defines the circumstances that, taking into consideration the categories of determination under subsection (c)—

''(i) favor the inclusion of an individual on a panel;

''(ii) favor a waiver of a conflict of interest requirement for an individual on a panel;

''(iii) favor a limited waiver of a conflict of interest requirement for an individual on a panel; and

"(iv) disfavor the inclusion of an individual on a panel;

"(B) that gives greater priority to consideration of an individual's net worth over consideration of absolute dollar value of an involvement in evaluating the magnitude of an involvement for purposes of making a determination under subsection (c);

"(C) that defines how financial interests imputed to an individual bear upon his or her eligibility for service on a panel or for service at a meeting of a panel;

"(D) that clarifies and improves the processes to ensure disclosure of, and to verify the accuracy of, financial interests imputed to an individual; and

"(E) to ensure consistency within and among the centers of the Food and Drug Administration in the issuance of determinations under subsection (c).

"(3) PERIODIC REVIEW.—At least once every 5 years, the Secretary shall review the guidance described under paragraph (2) and update such guidance as necessary.".

(b) REVIEW BY INSPECTOR GENERAL.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall, on an ongoing basis, conduct a review of the financial interests of a representative sample of individuals who have served on a panel (as defined in section 712 of the Federal Food, Drug, and Cosmetic Act) (as added by subsection (a)) of the Food and Drug Administration.

(2) SUBMISSION OF REPORT.—As part of the semiannual report required under section 5 of the Inspector General Act of 1978 (5 U.S.C. App.), the Inspector General of the Department of Health and Human Services shall include—

(A) the results of the review conducted under paragraph (1); and

(B) any findings with respect to an individual being rewarded or otherwise compensated by a sponsor of a product or a sponsor of a competing product for performance as a member of a panel of the Food and Drug Administration which considered the product or a competing product, or the absence of any such findings.

(c) CONFORMING AMENDMENT.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.